K051715

AUG 2 - 2005

INFINITT

510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
March 18, 2003

Submitter's Information: 21 CFR 807.92(a)(1)

INFINITT Co., Ltd.
Mr. Samuel Choi, Director Research & Development Department
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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name: STARPACS Dental™
Common Name: Picture Archiving Communications System
Device Classification: 892.2050
Product Code: LLZ
Classification Name: System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

	Predicate 1	Predicate 2
510(k) Number	K031013	K041078
Product Code	LLZ	LLZ
Product Name	INFINTT CO., LTD. STARPACS™ SYSTEM	SurgPLAN™ and PanPlan™
Decision Date	04/17/2003	12/23/2004

Device Description: 21 CFR 807 92(a)(4)

STARPACS Dental™ is a new software application that has been developed to handle digital templates for dental implants, which are placed over digital dental images. The overlay of digital templates onto digital dental images is useful in planning dental implants. The software is used together with the existing STARPACS solution (one of the predicate devices K031013). In addition to imaging and workflow features, STARPACS Dental allows dental implants simulations for dental implanting with the digital template library. STARPACS Dental is not intended to replace the skill and the experience of a qualified medical practitioner but to assist in surgical decisions and possibly to shorten surgery time.

STARPACS Dental software must be used by users who have the appropriate training and experience in the specialized field. Users should be aware of the limitations in the accuracy and correctness of the digital template displayed on the screen or printed from the PiViewSTAR PACS workstation. The quality of the digital

template is dependent of the correct calibration and settings of display device or printer, and the digital template.

Indications for Use: 21 CFR 807 92(a)(5)

StarPACS Dental™ device is a software package that scans (using direct digital capture using a solid state sensor) and stores those images. Additionally, the software has the ability to import DICOM images from volumetric data sets for visualization, analysis and reporting. The software allows the practitioner to perform surgical demonstrations for dental implant planning, cephlometric analysis, measurements and bone graft visualizations. The purpose of the software is to provide the doctor with a convenient method for visualization of these multiple imaging modalities, facilitates communication between multiple practitioners and to demonstrate treatment plan for the patient. Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for STARPACS Dental™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate devices. STARPACS Dental™ has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the potential hazards have been classified as "Minor".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 - 2005

INFINITT Co., Ltd.
% Mr. Carl Alletto
Official Correspondent
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

Re: K051715
Trade/Device Name: StarPACS Dental™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: April 27, 2005
Received: June 27, 2005

Dear Mr. Alletto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

PACS, RIS, 3D and Beyond
INFINITT

(Indications for Use Form)

510(k) Number: K051715

Device Name:
INFINITT Co. Ltd. **StarPACS Dental**™ device

Indications for Use:

StarPACS Dental™ device is a software package that scans (using direct digital capture using a solid state sensor) and stores those images. Additionally, the software has the ability to import DICOM images from volumetric data sets for visualization, analysis and reporting. The software allows the practitioner to perform surgical demonstrations for dental implant planning, cephlometric analysis, measurements and bone graft visualizations. The purpose of the software is to provide the doctor with a convenient method for visualization of these multiple imaging modalities, facilitates communication between multiple practitioners and to demonstrate treatment plan for the patient.

Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051715